

UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

In re :
Inspection of :
: NO. 22-mj-136
KVK Tech, Inc. :
located at 110 Terry Drive & 100 Campus Drive :
Newtown, PA 18940 :

APPLICATION FOR INSPECTION WARRANT

TO THE HONORABLE UNITED STATES MAGISTRATE JUDGE:

Jean G. Kulp, Area Director of the Allentown Area Office, Occupational Safety and Health Administration (OSHA), United States Department of Labor, hereby applies for a warrant pursuant to section 8 of the Occupational Safety and Health Act of 1970 (OSH Act or the Act), 29 U.S.C. § 657, to return to the workplace described in the above caption to complete certain inspection activities which OSHA was unable to complete during the period provided by a previous inspection warrant. As grounds for the issuance of the warrant, after first being sworn, I depose and state:

1. I am the Area Director of OSHA's Allentown Area Office. In that capacity, I supervise the inspection activities of OSHA's Compliance Safety and Health Officers assigned to the Allentown Area Office. Moreover, I have the responsibility of making applications for inspection warrants under sections 8(a) and 8(f)(1) of the Act, 29 U.S.C. §§ 657(a) and 657(f)(1).
2. KVK Tech, Inc. is a corporation engaged in the business of pharmaceutical preparation manufacturing.

3. KVK Tech, Inc. is an employer within the meaning of section 3(5) of the Act, 29 U.S.C. § 652(5), in that it employs employees within the meaning of section 3(6) of the Act, 29 U.S.C. § 652(6), in a business affecting commerce.

4. The facilities described in the caption were originally selected for inspection as a result of a referral made by Aaron McKivigan, a special agent of the United States Department of Labor, Office of Inspector General (USDOL-OIG).

5. Pursuant to an affidavit sworn out by a Criminal Investigator of the Food and Drug Administration (FDA), a search and seizure warrant was issued by the United States District Court for the Eastern District of Pennsylvania (EDPA) for the KVK worksites located at 100 Campus Drive, Newtown, PA 18940, 110 Terry Drive, Newtown, PA 18940 and 114 Pheasant Run, Newtown, PA 18940. These search and seizure warrants were executed by FDA Special Agents, USDOL-OIG Special Agents (including S.A. McKivigan), and Office of Homeland Security Special Agents. The search and seizure warrant execution on all three facilities began on July 29, 2021.

6. On July 29, 2021, during the search, S.A. McKivigan observed potential safety and health hazards and documented them in photographs.

7. Later that same day, S.A. McKivigan contacted the Allentown OSHA office, spoke to the area director, and described hazardous conditions that he had personally observed at the 100 Terry Drive and 100 Campus Drive facilities during the execution of the warrant at the facilities. S.A. McKivigan also provided the photographs he had taken. In addition, S.A. McKivigan described hazardous conditions at the facility that had come to his attention through witness statements that had been submitted to his office. A Referral Report, which set forth the specific concerns observed by S.A. McKivigan was attached as Exhibit A to the previously

submitted Application for an Inspection Warrant; S.A. McKivigan also provided a sworn declaration; and photographs S.A. McKivigan took were also attached as Exhibit B to the previously submitted Application. The previous Application for an Inspection Warrant and the accompanying exhibits are incorporated by reference here and attached as exhibits to this Application.

8. Prior to submitting the previous Application for an Inspection Warrant, when OSHA compliance officers arrived at the facilities on July 29, 2021, KVK Tech, Inc. refused to allow OSHA to conduct its inspection.

9. OSHA therefore applied to this Court for an inspection warrant on August 26, 2021, pursuant to 29 U.S.C. § 657. *See In re Inspection of KVK Tech, Inc.*, No. 21-mj-1350 (E.D. Pa.). The Application offered probable cause in support of the warrant by showing “a reasonable belief that a violation has been or is being committed.” With the evidence to establish a reasonable belief that KVK’s employees were being exposed to unsafe conditions that violate the OSH Act and its standards, this Court issued the warrant that same day.

10. The original warrant authorized OSHA to conduct an evaluation of the hazards set forth in the exhibit to the Application, along with any hazards in plain view. The hazards in the previous Application’s Exhibit A included reports that employees tested “positive for the narcotic drugs manufactured in the facility. This is not because of anything the employees are doing improperly, but because of their prolonged exposure to the particulate matter in the drug manufacturing process without having the proper PPE or ventilation in the facility.”

11. The warrant required the inspection of the workplace to “commence within seven (7) working days of the issuance of this warrant. The inspection and investigation shall proceed for no longer than ten (10) consecutive working days, which shall commence to run upon the

initiation of the inspection, unless the period for inspection is enlarged by further order of the Court.”

12. After the original warrant was issued on August 26, 2021, the inspection commenced that same day and continued until September 9, 2021.

13. Although OSHA has not yet made any final determinations or issued any citations, OSHA has thus far identified multiple potential violations, including:

a. Deficiencies identified in the company’s flammable storage room related to improper design and construction of the room and electrical hazards.

b. Employee exposures to oxycodone dust in the Pill Compression Room at approximately 10 times the employer’s own Occupational Exposure Limit (OEL), which is an exposure limit established by an outside company (Affygility Solutions) that the employer previously hired to identify unsafe levels of oxycodone exposure. Exposure to high levels of oxycodone dust can have multiple serious health consequences.

c. Potential violations related to a failure to train employees under OSHA’s Hazard Communication Program.

d. Potential violations related to deficiencies in the company’s respiratory protection program, personal protective equipment, and housekeeping.

14. While OSHA was able to inspect for these issues in certain areas of the workplace, OSHA was not able to inspect in other areas of the workplace that were authorized by the previous warrant. In particular, certain operations at KVK Tech, Inc. were not active and were therefore not available for inspection during the original 10-day warrant period. OSHA needs to conduct sampling for oxycodone exposure in these areas. These operations included:

- a. three mixing/blending rooms in which employees work with very large mixers;
- b. the dispensing/sifting rooms in which employees dispense bulk ingredients using a stainless-steel scoop; and
- c. the coating area in which dust is removed from tablets using a vibrator.

15. In addition to inspecting these new areas of the workplace which were not operating during the original 10-day warrant period, OSHA would also conduct additional sampling in the Pill Compression Room. Based on the oxycodone dust levels already sampled, which were significantly higher than anticipated, OSHA would re-sample using refined sampling methods, including both air sampling and wipe sampling, which will better quantify the exposure levels in this area.

16. The oxycodone dust at issue is both an inhalation and an ingestion hazard. Oxycodone is a Schedule II narcotic controlled substance. *See* 21 C.F.R. § 1308.12. Schedule II controlled substances are drugs that have “a high potential for abuse,” and which “may lead to severe psychological or physical dependence.” 21 U.S.C. § 812(b)(2).

17. OSHA now seeks authority to return to the workplace to inspect the operations of this worksite that were not available during the prior warrant period, and to perform additional sampling in the Pill Compression room. In particular, returning to the worksite pursuant to a second warrant would allow OSHA to conduct air sampling and wipe sampling in these areas to determine the levels of employee exposure to oxycodone dust in the air and on work surfaces.

18. In addition, OSHA would be able to take wipe samples to evaluate the oxycodone dust contamination that might exist in the change room, in the lunch room, and on employees’ clothing and hands, to determine whether cleaning procedures are deficient and creating an

ingestion hazard. As noted above, based on the oxycodone dust levels already sampled, which were significantly higher than anticipated, OSHA would re-sample using refined sampling methods.

19. OSHA would also be able to evaluate the employer's ventilation system and respirator program based on information that was only provided by the employer after the original 10-day warrant period. Also, during the original 10-day warrant period, OSHA did not have an opportunity to sample during the process of employees cleaning their respirators after their shifts were completed, which would be done when returning to the site.

20. For these reasons, OSHA is seeking a second warrant to return to the worksite to complete its inspection.

21. While OSHA has authority to conduct inspections of places of employment, 29 U.S.C. § 657, the Fourth Amendment's Warrant Clause applies to OSHA inspections. *See Marshall v. Barlow's, Inc.*, 436 U.S. 307 (1978). Therefore, OSHA must obtain an administrative warrant to conduct an inspection if the employer denies entry. The relaxed administrative probable cause standard governing the warrant application requires a showing of "specific evidence" that a violation exists. *See Martin v. International Matex Tank Terminals-Bayonne*, 928 F.2d 614, 622 (3d Cir. 1991).

22. Warrants for OSHA inspections may be based on, among other things, "probable cause to inspect by specific evidence of violations at the facility." *Id.* at 622. In the case of non-employee referrals, such probable cause exists if there is specific evidence sufficient to establish "a reasonable belief that a violation has been or is being committed." *Id.* at 625 (citation omitted).

23. OSHA's findings thus far, combined with information provided in the previous Application for Inspection Warrant, are sufficient to establish a reasonable belief that KVK's employees are exposed to unsafe conditions that violate the OSH Act and its standards. *See International Matex*, 928 F.2d at 625 (probable cause established where evidence included signed affidavit of OSHA inspector that she observed specific safety hazards during consensual inspection prior to employer refusing to allow inspection to continue). Specifically, there is probable cause based on specific evidence that establishes a reasonable belief that KVK's employees have been and are being exposed to violations of OSHA safe and health standards including, but not limited to: 29 C.F.R. §§ 1910.106, 1910.132, 1910.133, 1910.134, 1910.1200, 29 U.S.C. § 655, and § 5(a)(1) of the OSH Act.

24. As with the first warrant, the OSHA inspection will be conducted during regular working hours, within reasonable limits, and in a reasonable manner, and the compliance officer's credentials will be presented to KVK Tech, Inc.

25. The inspection and investigation will be limited in scope to the areas and hazards described above, and any hazards in plain view.

26. The inspection will also include the taking of photographs and/or videotaping for evidentiary purposes, and the questioning of employers, owners, operators, agents, and employees privately during working hours on KVK Tech, Inc. premises, as authorized by 29 C.F.R. § 1903.7(b). The inspection may also include the affixing of monitoring devices upon employees to determine the extent of their exposure to airborne contaminants and/or noise, as authorized by 29 C.F.R. § 1903.7(b).

27. The inspection and investigation shall also include the opportunity for a representative of the employer and a representative authorized by employees to accompany the

compliance officer during the physical inspection of the workplace, or the compliance officer shall consult with employees concerning matters of health and safety in the workplace if there is no authorized representative of employees pursuant to section 8(e) of the Act, 29 U.S.C. § 657(e) and 29 C.F.R. § 1903.8.

28. OSHA would return to the worksite within fourteen (14) days after the issuance of the warrant and would proceed for a reasonable period of time in order to fulfill the above sampling and testing objectives. OSHA would be permitted to return to the worksite on subsequent days if the operations in question are not active, or the sampling and testing cannot be completed within one day.

29. A return will be made to the Court within seven (7) calendar days after the completion of the inspection.

 Digitally signed by Jean G.
Kulp
Date: 2022.01.28 06:57:08
-05'00'

Jean G. Kulp, Area Director
Allentown Area Office
Occupational Safety and Health
Administration, Region III
United States Department of Labor

OF COUNSEL:

Seema Nanda
Solicitor of Labor

Oscar L. Hampton III
Regional Solicitor

Michael P. Doyle
Regional Counsel for OSHA

Judson H. Dean
Senior Trial Attorney

Post Office Address:

U.S. Department of Labor
1835 Market Street Mailstop SOL/22
Philadelphia, PA 19103
(215) 861-5139

Sworn to before me and subscribed in my presence this 28th day of January 2022. at (9:47 a.m.)

BY THE COURT:

/s/ Richard A. Lloret
RICHARD A. LLORET
U.S. MAGISTRATE JUDGE

UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

In re :
Inspection of :
KVK Tech, Inc. : NO. 22-mj-136
located at 110 Terry Drive & 100 Campus Drive :
Newtown, PA 18940 :

WARRANT FOR INSPECTION

TO: Jean G. Kulp, Area Director
Allentown Area Office
Occupational Safety and Health Administration,
Region III
United States Department of Labor

Application having been made, probable cause having been demonstrated, and a reasonable scope of inspection having been proposed:

IT IS HEREBY ORDERED that, pursuant to section 8 of the Occupational Safety and Health Act of 1970 (OSH Act), 29 U.S.C. § 657, YOU OR YOUR DULY DESIGNATED REPRESENTATIVE(S) ARE AUTHORIZED to enter the workplace of KVK Tech, Inc. at 100 Terry Drive, Newtown, Pennsylvania and 100 Campus Drive, Newtown, Pennsylvania during regular working hours and to inspect and investigate in a reasonable manner and to a reasonable extent the hazards set forth in the Application for Inspection Warrant, and any hazards in plain view. The inspection and investigation shall be conducted for the purposes of determining whether this employer is furnishing to its employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees, and whether this employer is complying with the occupational safety and health standards promulgated under the OSH Act and the rules, regulations and orders issued pursuant to the OSH Act.

Such inspection may include the taking of photographs and/or videotaping for evidentiary purposes and the questioning of any employer, owner, operator, agent or employee of the workplace privately on the employer's premises during working hours, as authorized by 29 C.F.R. § 1903.7(b). The inspection may also include the affixing of monitoring devices upon employees to determine the extent of their exposure to airborne contaminants and/or noise, as authorized by 29 C.F.R. § 1903.7(b).

The inspection and investigation shall also include the opportunity for a representative of the employer and a representative authorized by employees to accompany the Compliance Officer during the physical inspection of the workplace. If there is no authorized representative of the

employees, the Compliance Officer shall consult with employees concerning matters of health and safety in the workplace, pursuant to section 8(e) of the Act, 29 U.S.C. § 657(e), and 29 C.F.R. § 1903.8.

The inspection and investigation of the workplace shall commence within fourteen (14) days of the issuance of this warrant. The inspection and investigation shall proceed for a reasonable period of time to complete the inspection. OSHA may return to the worksite on subsequent days if the operations in question are not active, or the sampling and testing cannot be completed within one day.

A return shall be made to this Court within seven (7) calendar days following the completion of the inspection.

BY THE COURT:

Date: 1/28/2022

/s/ Richard A. Lloret
RICHARD A. LLORET
U.S. MAGISTRATE JUDGE

RETURN OF SERVICE

I hereby certify that a copy of the within warrant was duly served (indicate by check method used).

: on a duly authorized agent
: by leaving at principal office
: or place of business, to wit:
: _____
: _____
: _____

On the company named hereon

(Month) (Day) (Year)

(Name of person making service)

(Official Title)

RETURN

Inspection of the establishment described in the warrant was made
on _____, 2022.

Compliance Officer

UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

In re :
Inspection of :
KVK Tech, Inc. : NO. 21-mj-1350
located at 110 Terry Drive & 100 Campus Drive :
Newtown, PA 18940 :

APPLICATION FOR INSPECTION WARRANT

TO THE HONORABLE UNITED STATES MAGISTRATE JUDGE:

Jean G. Kulp, Area Director of the Allentown Area Office, Occupational Safety and Health Administration (OSHA), United States Department of Labor, hereby applies for a warrant pursuant to section 8 of the Occupational Safety and Health Act of 1970, 29 U.S.C. § 657, to inspect the workplace described in the above caption. As grounds for the issuance of the warrant, after first being sworn, I depose and state:

1. I am the Area Director of OSHA's Allentown Area Office. In that capacity, I supervise the inspection activities of OSHA's Compliance Safety and Health Officers assigned to the Allentown Area Office. Moreover, I have the responsibility of making applications for inspection warrants under sections 8(a) and 8(f)(1) of the Act, 29 U.S.C. §§ 657(a) and 657(f)(1).

2. KVK Tech, Inc. is a corporation engaged in the business of pharmaceutical preparation manufacturing.

3. KVK Tech, Inc. is an employer within the meaning of section 3(5) of the Act, 29 U.S.C. § 652(5), in that it employs employees within the meaning of section 3(6) of the Act, 29 U.S.C. § 652(6), in a business affecting commerce.

4. The facilities described in the caption have been selected for inspection as a result of a referral made by Aaron McKivigan, a special agent of the United States Department of Labor, Office of Inspector General (USDOL-OIG).

5. Pursuant to an affidavit sworn out by a Criminal Investigator of the Food and Drug Administration (FDA), a search and seizure warrant was issued by the United States District Court for the Eastern District of Pennsylvania (EDPA) for the KVK worksites located at 100 Campus Drive, Newtown, PA 18940, 110 Terry Drive, Newtown, PA 18940 and 114 Pheasant Run, Newtown, PA 18940. These search and seizure warrants were executed by FDA Special Agents, USDOL-OIG Special Agents (including S.A. McKivigan), and Office of Homeland Security Special Agents. The search and seizure warrant execution on all three facilities began on July 29, 2021.

6. On July 29, 2021, during the search, S.A. McKivigan observed potential safety and health hazards and documented them in photographs.

7. Later that same day, S.A. McKivigan contacted the Allentown OSHA office and spoke to the area director and described hazardous conditions that he had personally observed at the 100 Terry Drive and 100 Campus Drive facilities during the execution of the warrant at the facilities. S.A. McKivigan also provided the photographs he had taken. In addition, S.A. McKivigan described hazardous conditions at the facility that had come to his attention through witness statements that had been submitted to his office. A Referral Report, which sets forth the specific concerns observed by S.A. McKivigan, is attached hereto as Exhibit A. In addition, the declaration of S.A. Aaron McKivigan and the photographs he took are attached hereto as Exhibit B.

8. When OSHA compliance officers arrived at the facilities on July 29, 2021, KVK Tech, Inc. refused to allow OSHA to conduct its inspection.

9. While OSHA has authority to conduct inspections of places of employment, 29 U.S.C. § 657, the Fourth Amendment's Warrant Clause applies to OSHA inspections. *See Marshall v. Barlows, Inc.*, 436 U.S. 307 (1978). Therefore, OSHA must obtain an administrative warrant to conduct an inspection if the employer denies entry. The relaxed administrative probable cause standard governing the warrant application requires a showing of "specific evidence" that a violation exists. *See Martin v. International Matex Tank Terminals-Bayonne*, 928 F.2d 614, 622 (3d Cir. 1991).

10. Warrants for OSHA inspections may be based on employee complaints, programmed inspections pursuant to neutral administrative plans, or referrals from non-employees which establish "probable cause to inspect by specific evidence of violations at the facility." *Id.* at 622. In the case of non-employee referrals, such probable cause exists if there is specific evidence sufficient to establish "a reasonable belief that a violation has been or is being committed." *Id.* at 625 (citation omitted).

11. The allegations made by the special agent of the USDOL-OIG, as set forth in Exhibit A, are sufficient to establish a reasonable belief that KVK's employees are exposed to unsafe conditions that violate the OSH Act and its standards. *See International Matex*, 928 F.2d at 625 (probable cause established where evidence included signed affidavit of OSHA inspector that she observed specific safety hazards during consensual inspection prior to employer refusing to allow inspection to continue). Specifically, there is probable cause to believe KVK's employees may be exposed to violations of OSHA safety and health standards including, but not limited to: 29 C.F.R. § 1910.22, § 1910.106, § 1910.120, § 1910.132, § 1910.133, § 1910.134,

§ 1910.151, § 1910.155, § 1910.303, § 1910.332, § 1910.1000, § 1910.1200, and Section 5(a)(1) of the OSH Act.

12. The OSHA inspection will be conducted during regular working hours, within reasonable limits, and in a reasonable manner, and the compliance officer's credentials will be presented to KVK Tech, Inc.

13. The inspection and investigation will be limited in scope to an evaluation of the hazards set forth in Exhibit A and any hazards in plain view.

14. The inspection will also include the taking of photographs and/or videotaping for evidentiary purposes, and the questioning of employers, owners, operators, agents and employees privately during working hours on KVK Tech, Inc. premises, as authorized by 29 C.F.R. § 1903.7(b). The inspection may also include the affixing of monitoring devices upon employees to determine the extent of their exposure to airborne contaminants and/or noise, as authorized by 29 C.F.R. § 1903.7(b).

15. The inspection and investigation shall also include the opportunity for a representative of the employer and a representative authorized by employees to accompany the compliance officer during the physical inspection of the workplace, or the compliance officer shall consult with employees concerning matters of health and safety in the workplace if there is no authorized representative of employees pursuant to section 8(e) of the Act, 29 U.S.C. § 657(e) and 29 C.F.R. § 1903.8.

16. The inspection shall commence within seven (7) working days of the issuance of the warrant. The inspection shall proceed for no longer than ten (10) consecutive working days, which shall commence to run upon initiation of the inspection, unless the period for inspection is

enlarged by further order of the Court. Days on which this facility is not operating will not be counted as "working days."

17. A return will be made to the Court within seven (7) calendar days after the completion of the inspection.

Jean G.
Kulp


Digitally signed by
Jean G. Kulp
Date: 2021.08.26
12:31:04 -04'00'

Jean G. Kulp, Area Director
Allentown Area Office
Occupational Safety and Health
Administration, Region III
United States Department of Labor

OF COUNSEL:

Seema Nanda
Solicitor of Labor

Oscar L. Hampton III
Regional Solicitor

Michael P. Doyle
Regional Counsel for OSHA

Judson H. Dean
Senior Trial Attorney

Post Office Address:

U.S. Department of Labor
1835 Market Street Mailstop SOL/22
Philadelphia, PA 19103
(215) 861-5139

Sworn to before me and subscribed in my presence this 26th day of August 2021.

/s/ Marilyn Heffley
THE HONORABLE MARILYN HEFFLEY
UNITED STATES MAGISTRATE JUDGE

EX. A TO APPLICATION FOR INSPECTION WARRANT

U.S. Department of Labor

Occupational Safety and Health Administration

Referral Report

July 29, 2021 3:30 PM

Receipt Information				
RID	UPA Number	Receipt Date	Receipt Time	Receipt Type
0317900	1791661	07/29/2021	01:00 PM	Email
Electronic Complaint Number				

Establishment Name	KVK TECH INC.	Doing Business As (DBA)	
Related Inspections			
Industry & Ownership	Primary NAICS	325412 - Pharmaceutical Preparation Manufacturing	Ownership Private Sector
Type Of Business			

Site Information					
Street Address 1:	110 TERRY DRIVE AND 100 CAMPUS DRIVE				
Street Address 2:					
County:	BUCKS				
City:	NEWTOWN	State:	PA	Zip:	18940
Management Official					
Phone Number:	(215) 579-1842	Fax Numer:			

Business Address					
Street Address 1:	110 TERRY DRIVE AND 100 CAMPUS DRIVE				
Street Address 2:					
County:	BUCKS				
City:	Newtown	State:	PA	Zip:	18940
Country:	UNITED STATES OF AMERICA				

Mailing Address					
Street Address 1:	110 TERRY DRIVE AND 100 CAMPUS DRIVE				
Street Address 2:					
County:	BUCKS				

EX. A TO APPLICATION FOR INSPECTION WARRANT

City:	Newtown	State:	PA	Zip:	18940
Country:	UNITED STATES OF AMERICA				

HAZARD DESCRIPTION/LOCATION. Describe briefly the hazard(s) which you believe exist. Include the approximate number of employees exposed to or threatened by each hazard. Specify the particular building or worksite where the alleged violation exists.

1. There is no required fire suppression system in the HAZMAT storage room.
2. Most of the parts and replacement equipment used in the facility is shipped from India, and is not intended, or rated for use in an U.S. facility. One example of the air handling HVAC units on the roof of the buildings. These units were shipped from India and are rated for indoor use only, but are being used outside. The high voltage control panels for these units are covered in bubble wrap and secured by duct tape, but still get water inside from the elements. Water also leaks through these onto electronics in the manufacturing lines below. Air conditioners set up in the building do not provide sufficient ventilation.
3. When the company has to replace gas lines and valves inside the facility, they use cheaper parts and equipment rated for use to move water only. This results in regular and significant gas leaks around the fittings of the pipes.
4. Individuals, who are known not to be qualified electricians, are used to do repair work and run high voltage power lines to run the manufacturing equipment in the facility. The company owner brings these laborers in after business hours to do this work so the employees don't see who is performing the work and become alerted to the danger of the electrical systems in the facility.
5. The HR and Drug Testing Manager both reported many of the employees test positive for the narcotic drugs manufactured in the facility. This is not because of anything the employees are doing improperly, but because of their prolonged exposure to the particulate matter in the drug manufacturing process without having the proper PPE or ventilation in the facility.
6. Flooring panels are removed creating trip/fall hazards and exposure to electrical wiring at the 100 Campus Drive location.
7. The electrical panel area is not maintained in a clean and orderly condition. Pallets, electrical panels, and motors are being stored haphazardly at the 100 Campus Drive location.
8. Ceiling tiles have been removed allowing wiring to fall through the ceiling areas at the 110 Terry Drive location.
9. Gas odors coming from the boiler room at the 110 Terry Drive location.
10. Flammable liquids and other chemicals are not properly stored at the 110 Terry Drive location.
11. The dust collector/vacuum system is leaking and not sealed properly at the 100 Campus Drive location.
12. Emergency showers are partially blocked at the 110 Terry Drive location.
13. Chemical are stored in unlabeled containers in the labs at 110 Terry Drive location.
14. Hazardous Waste is improperly collected into containers alongside the processes at the 110 Terry Drive location.

Source Information			
Source Type	Other Federal Agency	If Other, Specify	
Source Name	Aaron McKivigan	Phone	(215) 446-3747
Source Address	UNITED STATES OF AMERICA		

EX. A TO APPLICATION FOR INSPECTION WARRANT

Source E-mail Address			
Send Referral Results?	Yes	Reason if no UPA results sent	

Referral Actions					
Action Date	Action Type	Date Response Due	Communication Method	Type of Letter-Reason	Other – Status
07/29/2021	Do Inspection = Y				
07/29/2021	Valid = Y				

Referral Responses				
Date Response Received	Type Response Received	Evaluation	Evaluated By	Other

RRI Investigation Information					
# Hospitalizations	# of Amputations	# of Eye Injuries	Event Date	Event Time	
Has this happened before?		Is the hazard still present?		Date employer's response sufficient to close investigation	

What was employee doing just before incident occurred?	
What happened?	
What was the injury or illness?	
What was the object or substance that directly harmed the employee?	

RRI Corrective Actions	
Corrective Action Keywords	
Additional Relevant Information	
Inadequate Employer Response Description	

EX. A TO APPLICATION FOR INSPECTION WARRANT

Program Information	
National Emphasis	
Local/State-Emphasis	
State Strategic Initiatives	

Additional Codes			
Code Type	Code ID	Code Value	Code Description

UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

In re :
Inspection of :
KVK Tech, Inc. : NO. _____
located at 110 Terry Drive & 100 Campus Drive :
Newtown, PA 18940 :

DECLARATION

I, Aaron D. McKivigan, state the following under 28 U.S.C. § 1746 and under penalty of perjury:

1. I am a Special Agent at the United States Department of Labor (USDOL) in the Office of Inspector General (OIG), specifically the Office of Investigations – Labor Racketeering & Fraud. My office is located at One Independence Mall, 615 Chestnut Street, Suite 703, in Philadelphia, Pennsylvania, 19106.
2. Pursuant to an affidavit sworn out by a Criminal Investigator of the Food and Drug Administration, a federal search and seizure warrant was issued by the United States District Court in the Eastern District of Pennsylvania for the properties of KVK Tech, Inc. located at 100 Campus Drive, Newtown, PA 18940, 110 Terry Drive, Newtown, PA 18940 and 114 Pheasant Run, Newtown, PA 18940.
3. This search and seizure warrant was executed by Special Agents of the Food and Drug Administration, the USDOL-OIG, and the Office of Homeland Security. The search and seizure warrant execution on all three aforementioned facilities of KVK Tech, Inc. began on July 29, 2021 and ended on August 4, 2021.
4. While inside of these facilities, I observed the following safety and health hazards, which I documented with photographs (which are attached to this Declaration).

5. Flooring panels are removed creating trip/fall hazards and exposure to electrical wiring at the 100 Campus Drive location.
6. The electrical panel area is not maintained in a clean and orderly condition. Pallets, electrical panels, and motors are being stored haphazardly at the 100 Campus Drive location.
7. Ceiling tiles have been removed allowing wiring to fall through the ceiling areas at the 110 Terry Drive location.
8. Gas odors coming from the boiler room at the 110 Terry Drive location.
9. Flammable liquids and other chemicals are not properly stored at the 110 Terry Drive location.
10. The dust collector/vacuum system is leaking and not sealed properly at the 100 Campus Drive location.
11. Emergency showers are partially blocked at the 110 Terry Drive location.
12. Chemical are stored in unlabeled containers in the labs at 110 Terry Drive location.
13. Hazardous Waste is improperly collected into containers alongside the processes at the 110 Terry Drive location.
14. Prior to the execution of the search warrant, I had also obtained information through interviews of employees of KVK Tech, Inc. regarding the following additional safety and health hazards.
15. There is no required fire suppression system in the HAZMAT storage room.
16. Most of the parts and replacement equipment used in the facility are shipped from India, and are not intended or rated for use in an U.S. facility. One example is the air handling HVAC units on the roof of the buildings. These units were shipped from India and are rated for indoor use only, but are being used outside. The high voltage control panels for these units are covered in bubble wrap and secured by duct tape, but still get water inside from the elements. Water also leaks through these onto electronics in the manufacturing lines below. Air conditioners set up in the building do not provide sufficient ventilation.

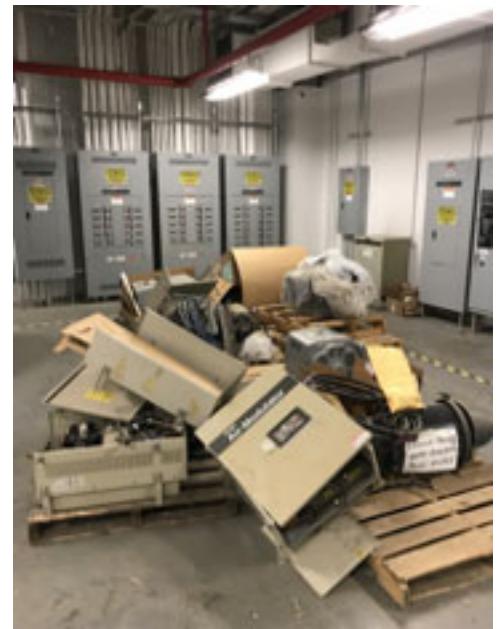
17. When the company has to replace gas lines and valves inside the facility, they use cheaper parts and equipment rated for use to move water only. This results in regular and significant gas leaks around the fittings of the pipes.
18. Individuals, who are known not to be qualified electricians, are used to do repair work and run high voltage power lines to run the manufacturing equipment in the facility. The company owner brings these laborers in after business hours to do this work so the employees don't see who is performing the work and become alerted to the danger of the electrical systems in the facility.
19. The HR and Drug Testing Manager both reported many of the employees test positive for the narcotic drugs manufactured in the facility. This is not because of anything the employees are doing improperly, but because of their prolonged exposure to the particulate matter in the drug manufacturing process without having the proper PPE or ventilation in the facility.
20. I have provided all of the above information and my photographs to Jean Kulp, Area Director of the Allentown OSHA Area Office.

Aaron D.
McKivigan

Digitally signed by Aaron D.
McKivigan
Date: 2021.08.24 10:12:44
-04'00'

Aaron D. McKivigan

Dated: 08/24/2021









U.S. Department of Justice

United States Attorney

Eastern District of Pennsylvania

Anthony D. Scicchitano
Direct Dial
Fax
E-mail Address

Assistant United States Attorney
(215) 861-8380
(215) 861-8618
anthony.scicchitano@usdoj.gov

615 Chestnut Street
Suite 1250
Philadelphia, Pennsylvania 19106-4476
(215) 861-8200

August 26, 2021

Via Email

The Honorable Marilyn Heffley
United States Magistrate Judge
3000 United States Courthouse
601 Market Street
Philadelphia, PA 19106

Re: Application for Inspection Warrant for KVK Tech, Inc.

Dear Judge Heffley:

I have enclosed for the Court's review an Application for Inspection Warrant and a proposed Inspection Warrant pursuant to section 8 of the Occupational Safety and Health Act of 1970 (the Act), 29 U.S.C. § 657. I have also enclosed a Referral Report and the supporting Declaration of Special Agent Aaron McKivigan from the U.S. Department of Labor – Office of Inspector General (USDOL-OIG). The application seeks a warrant to inspect facilities operated by KVK Tech, Inc. (KVK). As set forth in the application, Special Agent McKivigan personally observed safety and health hazards at the facilities and made a referral to the Occupational Safety and Health Administration (OSHA). When OSHA arrived at the facilities, KVK refused to allow OSHA to conduct its inspection.

While OSHA has authority to conduct inspections of places of employment, 29 U.S.C. § 657, the Fourth Amendment's Warrant Clause applies to OSHA inspections. *See Marshall v. Barlows, Inc.*, 436 U.S. 307 (1978). Therefore, OSHA must obtain an administrative warrant to conduct an inspection if the employer denies entry. The relaxed administrative probable cause standard governing the warrant application requires a showing of "specific evidence" that a violation exists. *See Martin v. International Matex Tank Terminals-Bayonne*, 928 F.2d 614, 622 (3d Cir. 1991).

Warrants for OSHA inspections may be based on employee complaints, programmed inspections pursuant to neutral administrative plans, or referrals from non-employees which establish "probable cause to inspect by specific evidence of violations at the facility." *Id.* at 622. In the case of non-employee referrals, such probable cause exists if there is specific evidence sufficient to establish "a reasonable belief that a violation has been or is being committed." *Id.* at 625 (citation omitted).

The allegations made by the Special Agent of the USDOL-OIG, as set forth in Exhibit A, are sufficient to establish a reasonable belief that KVK's employees are exposed to unsafe conditions that violate the OSH Act and its standards. *See International Matex*, 928 F.2d at 625 (probable cause established where evidence included signed affidavit of OSHA inspector that she

observed specific safety hazards during consensual inspection prior to employer refusing to allow inspection to continue). The referral and supporting declaration provide “specific evidence” of such violations. USDOL-OIG Special Agent McKivigan personally observed specific hazardous conditions at the worksites and provided clear photographs of those hazardous conditions, all of which are set forth in OSHA’s Referral Report (Ex. A to the Application) and his Declaration and photographs (Ex. B to the Application). The supporting materials provide the specific locations of those violations. Because the application is based on a credible referral with a clear basis for the allegations, and because the referral, declaration, and photographs amount to specific evidence that establishes a reasonable belief that a violation has been or is being committed, the relevant probable cause standard is satisfied.

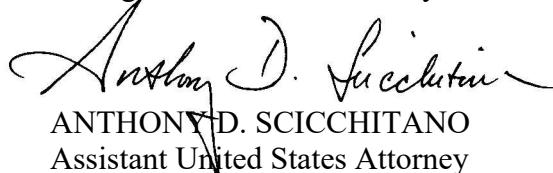
In addition, the scope of the proposed warrant here is tailored to the violations at issue. The proposed warrant only seeks to address the violations depicted in Special Agent McKivigan’s declaration.

We respectfully request that the Court review the enclosed Application for Inspection Warrant and the accompanying materials at your earliest convenience. Jean Kulp, the Area Director of the OSHA Allentown Area Office, is available to swear out the Application, and Special Agent McKivigan is also available if necessary.

We look forward to discussing this with Your Honor.

Respectfully,

JENNIFER ARBITTER WILLIAMS
Acting United States Attorney


ANTHONY D. SCICCHITANO
Assistant United States Attorney

Enclosures:

Application for Inspection Warrant with Exhibits A and B
Proposed Inspection Warrant

UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

In re :
Inspection of :
KVK Tech, Inc. : NO. 21-mj-1350
located at 110 Terry Drive & 100 Campus Drive :
Newtown, PA 18940 :

WARRANT FOR INSPECTION

TO: Jean G. Kulp, Area Director
Allentown Area Office
Occupational Safety and Health Administration,
Region III
United States Department of Labor

Application having been made, probable cause having been demonstrated, and a reasonable scope of inspection having been proposed:

IT IS HEREBY ORDERED that, pursuant to section 8 of the Occupational Safety and Health Act of 1970, 29 U.S.C. § 657, YOU OR YOUR DULY DESIGNATED REPRESENTATIVE(S) ARE AUTHORIZED to enter the workplace of KVK Tech, Inc. at 100 Terry Drive, Newtown, Pennsylvania and 100 Campus Drive, Newtown, Pennsylvania during regular working hours and to inspect and investigate in a reasonable manner and to a reasonable extent for purposes of a comprehensive safety and health inspection.

The safety and health inspection shall entail an evaluation of the hazards set forth in Exhibit A to the Application for Warrant, and any hazards in plain view, to determine whether this employer is furnishing to its employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees, and whether this employer is complying with the occupational safety and health standards promulgated under the OSH Act and the rules, regulations and orders issued pursuant to the OSH Act.

Such inspection may include the taking of photographs and/or videotaping for evidentiary purposes and the questioning of any employer, owner, operator, agent or employee of the workplace privately on the employer's premises during working hours, as authorized by 29 C.F.R. § 1903.7(b). The inspection may also include the affixing of monitoring devices upon employees to determine the extent of their exposure to airborne contaminants and/or noise, as authorized by 29 C.F.R. § 1903.7(b).

The inspection and investigation shall also include the opportunity for a representative of the employer and a representative authorized by employees to accompany the Compliance Officer during the physical inspection of the workplace. If there is no authorized representative of the employees, the Compliance Officer shall consult with employees concerning matters of health and safety in the workplace, pursuant to section 8(e) of the Act, 29 U.S.C. § 657(e), and 29 C.F.R. § 1903.8.

The inspection and investigation of the workplace shall commence within seven (7) working days of the issuance of this warrant. The inspection and investigation shall proceed for no longer than ten (10) consecutive working days, which shall commence to run upon the initiation of the inspection, unless the period for inspection is enlarged by further order of the Court. Days on which the workplace is not operating will not be counted as "working days."

A return shall be made to this Court within seven (7) working days following the completion of the inspection.

BY THE COURT:

Date: 8/26/2021

/s/ Marilyn Heffley
THE HONORABLE MARILYN HEFFLEY
UNITED STATES MAGISTRATE JUDGE

RETURN OF SERVICE

I hereby certify that a copy of the within warrant was duly served (indicate by check method used).

: on a duly authorized agent
: by leaving at principal office
: or place of business, to wit:
: _____
: _____
: _____

On the company named hereon

(Month) (Day) (Year)

(Name of person making service)

(Official Title)

RETURN

Inspection of the establishment described in the warrant was made
on _____, 2021.

Compliance Officer



U.S. Department of Justice
United States Attorney
Eastern District of Pennsylvania

Anthony D. Scicchitano
Direct Dial
Fax
E-mail Address

Assistant United States Attorney
(215) 861-8380
(215) 861-8618
anthony.scicchitano@usdoj.gov

615 Chestnut Street
Suite 1250
Philadelphia, Pennsylvania 19106-4476
(215) 861-8200

January 28, 2022

Via Email

The Honorable Richard A. Lloret
United States Magistrate Judge
3006 United States Courthouse
601 Market Street
Philadelphia, PA 19106

Re: Application for Inspection Warrant for KVK Tech, Inc.

Dear Judge Lloret:

I have enclosed for the Court's review an Application for Inspection Warrant and a proposed Inspection Warrant pursuant to section 8 of the Occupational Safety and Health Act of 1970 (the Act), 29 U.S.C. § 657. The application seeks an administrative inspection warrant to inspect facilities operated by KVK Tech, Inc. (KVK). I have also enclosed in support of the Application a copy of the previous Application for Inspection Warrant and its accompanying exhibits that pertain to the same workplace. As set forth in the submissions, a special agent with the U.S. Department of Labor Office of Inspector General personally observed safety and health hazards at the facilities and made a referral to the Occupational Safety and Health Administration (OSHA). OSHA applied for, received, and executed an Inspection Warrant focusing on those observed violations at KVK. After identifying multiple potential violations, OSHA now seeks a renewed inspection warrant to inspect certain parts of the workplace that were not operational during the previous inspection and seeks an opportunity to inspect in more detail the employees' oxycodone exposure at approximately ten times the employer's own occupational exposure limit.

While OSHA has authority to conduct inspections of places of employment, 29 U.S.C. § 657, the Fourth Amendment's Warrant Clause applies to OSHA inspections. *See Marshall v. Barlow's, Inc.*, 436 U.S. 307 (1978). Therefore, OSHA must obtain an administrative warrant to conduct an inspection if the employer denies entry. The relaxed administrative probable cause standard governing the warrant application requires a showing of "specific evidence" that a violation exists. *See Martin v. International Matex Tank Terminals-Bayonne*, 928 F.2d 614, 622 (3d Cir. 1991).

Warrants for OSHA inspections may be based on, among other things, "probable cause to inspect by specific evidence of violations at the facility." *Id.* at 622. In the case of non-employee referrals, such probable cause exists if there is specific evidence sufficient to establish "a reasonable belief that a violation has been or is being committed." *Id.* at 625 (citation omitted).

The current Application for Inspection Warrant, coupled with the prior Application for Inspection Warrant attached as an exhibit, are sufficient to establish a reasonable belief that KVK's employees are exposed to unsafe conditions that violate the OSH Act and its standards. *See International Matex*, 928 F.2d at 625 (probable cause established where evidence included signed affidavit of OSHA inspector that she observed specific safety hazards during consensual inspection prior to employer refusing to allow inspection to continue). The USDOL-OIG referral and supporting declaration provided "specific evidence" of violations that were occurring in the KVK workplace. While a previous inspection warrant that was granted covered those issues, specific operations of KVK were not operational at the time of the previous inspection and were therefore not available to be inspected. In addition, the previous inspection revealed that KVK employees are being exposed to oxycodone dust at approximately ten times KVK's own occupational exposure limit; OSHA now seeks to inspect this potential violation in more detail using refined sampling methods. Because this application is based on credible information with a clear basis for the allegations, and because the application and supporting materials amount to specific evidence that establishes a reasonable belief that a violation has been or is being committed, the relevant probable cause standard is satisfied.

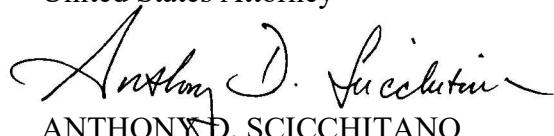
In addition, the scope of the proposed warrant here is tailored to the violations at issue. The proposed warrant only seeks to address the violations outlined in the Application and any others in plain view.

We respectfully request that the Court review the enclosed Application for Inspection Warrant and the accompanying materials at your earliest convenience. Jean Kulp, the Area Director of the OSHA Allentown Area Office, is available to swear out the Application.

We look forward to discussing this with Your Honor.

Respectfully,

JENNIFER ARBITTIER WILLIAMS
United States Attorney


ANTHONY D. SCICCHITANO
Assistant United States Attorney

Enclosures:

Application for Inspection Warrant with Exhibit
Proposed Inspection Warrant